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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/617,573

07/11/2003

Ellen Filvaroff

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EXAMINER

JIANG, DONG

ART UNIT

PAPER NUMBER

1646

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/617,573	Applicant(s) FILVAROFF ET AL.	
	Examiner DONG JIANG	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 61,63,64,68,69,76,77,80-84 and 86 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 61,63,64,68,69 and 84 is/are allowed.
- 6) ☒ Claim(s) 76,77,80-83 and 86 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED OFFICE ACTION

Applicant's amendment filed on 11 March 2009 is acknowledged and entered. Following the amendment, claims 65, 66, 78 and 79 are canceled, and claims 61 and 76 are amended.

Currently, claims 61, 63, 64, 68, 69, 76, 77, 80-84 and 86 are pending and under consideration.

Withdrawal of Objections and Rejections:

All objections and rejections of claims 65, 66, 78 and 79 are moot as the applicant has canceled the claims.

The scope of enablement rejection of claims 61, 63, 64, 68, 69, 76, 77, 80-84 and 86 under 35 U.S.C. 112, first paragraph is withdrawn in view of applicant's amendment.

Rejections under 35 U.S.C. §112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 76, 77 and 80-83 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the last Office Action mailed on 03 February 2009, at pages 4-6.

Applicants argument filed on 11 March 2009 has been fully considered, but is not deemed persuasive for the reasons below.

At pages 5-6 of the response, the applicant argues that the application describes in detail PRO polypeptide variants of the invention and how one skilled in the art could obtain PRO polypeptide sequences with at least 85% sequence identity to polypeptides of the invention (using the ALIGN-2 program), thereby providing a means for identifying polypeptides with at

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least 85% sequence identity to SEQ ID NO:6; and that the inventors also provided sufficient description to show they had possession of antibodies that bind polypeptides with at least 85% sequence identity to SEQ ID NO:6, as the specification sufficiently describes antibodies that bind the polypeptide of SEQ ID NO:6, and methods of making antibodies are replete throughout the specification. Applicants further argue that "Example 13: Antibodies To A Single Protein" on page 46 of the Written Description Training Materials states that "...the routine art-recognized method of making antigen-specific antibodies, the adequate description of antigen X...and the fact that antibody technology was well developed and mature, one of skill in the art would have recognized that the disclosure of the adequately described antigen X put the applicant in possession of antibodies which bind to antigen X", thus, since an antibody that recognizes polypeptides with at least 85% sequence identity to SEQ ID NO:6 is sufficiently described and the fact that one skilled in the art would have recognized that the specification sufficiently described methods for making antibodies to such polypeptide, it would have been obvious that applicants had possession of the invention as claimed. This argument is not persuasive because the issue is not whether a skilled artisan would know how to determine % sequence identity of two polypeptides, nor whether a method of making antibody had been well established, rather, the issue is that a skilled artisan cannot envision the detailed structure of the encompassed variants. All the specification discloses, with this regard, is a single polypeptide of SEQ ID NO:6, and no variant of any kind for SEQ ID NO:6 was ever identified or particularly described. Hence, there is accordingly no written description of the claimed polypeptides, other than the one identified as SEQ ID NO:114. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. Further, the specification provides no correlation between the amino acid sequence of SEQ ID NO:6 and epitopes thereof that are specific for SEQ ID NO:6. Therefore, it would be completely unpredictable as to which amino acids can be changed or unchanged in order to retain the antigenicity specific for SEQ ID NO:6. As such, the specification provides no written support for the antibodies to the % variant encompassed by the present claims. Furthermore, the current situation differs from that of

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"Example 13" in the Written Description Training Materials as no variant of antigen X is indicated. For the reasons above, the rejections is maintained.

Conclusion:

Claims 61, 63, 64, 68, 69 and 84 are allowable.

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Advisory Information:

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on 9:30 am - 7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Dong Jiang/
Primary Examiner, Art Unit 1646
6/16/09